United States Department of Agriculture | Agricultural Research Service | Southern Plains Area | Stuttgart National Aquaculture Research Center
P.O. Box 860; 2955 Hwy 130 E.
Stuttgart, AR 72160-0860

Comments on "PROPOSALS TO INCREASE THE AVAILABILITY OF APPROVED ANIMAL DRUGS FOR MINOR SPECIES AND MINOR USES."

A. MODIFICATION OF EXTRALABEL PROVISIONS

- Will the proposed modification of extralabel provisions and suggested sunset period provide adequate and appropriate temporary relief until approved products are made available, or will it serve as a disincentive to the prusuit of approvals?

Modification of extralabel provisions of AMDUCA would make possible the use of antibiotics in fish feeds, and this is needed. In the catfish industry there are 3 FDA approved food additive antibiotics, but realistically there is only 1, Romet-30. Terramycin is usable only in sinking formulations of fish feed and there are few catfish producers using sinking feeds. Sulfamerazine is no longer on the market. There are some problems with Romet-30; it is unpalatable and expensive.

A sunset clause would only push back the day when the provisions of AMDUCA take effect. Unless some plan is adopted to hasten and simplify drug approval for aquaculture usage, in 10 years there will likely be only 1 or 2 more approved feed additives whether the extralabel provisions of AMDUCA are modified or not.

Would it be possible for FDA to modify its INAD policy so as to allow fish producers who need to use extralabel medicated feeds to do so in conjunction with an INAD coordinator who could use the treatment episode to establish efficacy?

- Should the proposed modifications be extended to include reproductive hormones and implants?

It is not clear how the proposed modifications relate to reproductive hormones and implants. Reproductive hormones might be in a feed additive form, but implants?

B. REMOVAL OF DISINCENTIVES

- Will the suggested strategies be sufficinet to remove the existing regulatory disincentives?

1. Lack of enforcement resources. **This is not thought to be a serious disincentive. True there are few therapeutic drugs approved for fish, however there are no unapproved drugs in competition with any drug that is now under consideration for FDA approval.**

2. Changes in the Standard for Regulatory Action. **If this change were made it should simplify enforcement and reduce the potential manpower and funding now committed to enforcement.**

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3. Assurance that an Existing Approval Would Not Be at Risk. **It is questionable whether this is a serious disincentive. Does FDA have the authority to "open up" a prior approval for review? If data from the parent application is insufficient to support claims made for a minor use drug, it simply doesnot support the minor use claim and it should not jeapordize the parent application in anyway. If data do support a minor use claim, that says nothing about the quality of the parent application which was for a different purpose submitted under different (?) requirements. Grandfathering is still recognized.**

In general, the main disincentive was not addressed--it is not profitable to try to market minor use drugs. The single proposal that was made that would address this was a significant tax incentive.

C. ENHANCEMENT OF EXISTING PROGRAMS FOR DATA DEVELOPMENT

- Are there additional existing congressional research funds which could be expanded for minor use research?

These are good proposals and would directly affect the amount of drug research undertaken. Cooperative Research and Development Agreements (CRADA's)should also be encouraged in USDA, Interior, and Commerce. CRADA's are commonly developed between FDA laboratories and private groups and in ARS laboratories in areas other than minor use drugs. Pharmaceutical companies and producers of other aquaculture chemicals may not be aware of the existence of CRADA's.

- Would the proposed database be useful to parties interested in furthering the approval of minor use products? If so, how might it be developed most cost effectively?

What real purpose would be served by this database? To acquaint those with a curiosity to minor diseases and drugs. Any person with a professional interest in a minor disease or drug will have the information they need. So-called scientific databases often contain only superficial information.

E. DATA SHARING BY MAJOR SPECIES NADA HOLDERS

- Is it fair to require the sharing of data?

No! And fair is not the issue. It is intrusive. Let the minor use sponsor negotiate with the pioneer sponsor to purchase or otherwise agree upon use of the data, but don't attempt to create law saying FDA can horn in on any data it choses.

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F. CREATION BY STATUTE OF A "MINOR USE ANIMAL DRUG" PROGRAM

- Would a statutory designation of "minor use animal drug" similar to the statutory designation of "human orphan drug" be useful?
  Yes.

- Are the incentives associated with this strategy a necessary component of the overall proposed "Minor Use Animal Drug Program"?
  Yes.

I. INTERNATIONAL HARMONIZATION

- Could non-governmental input facilitate equivalency determinations?
  That would appear to be the most efficient way in combination with agency activity.

- Are there sufficient numbers of foreign approvals to justify establishing this program?
  Absolutely!

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